

MAY 14 2004

510 (k) Summary of Safety and Effectiveness for Table Tilt Device

K033316

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Rainer Birkenbach

Summary Date: January 8, 2004

Device Name:

Trade name: Robotic Tilt Module

Common/Classification Name: Table Tilt Device

Predicate Device: Med-Tec 6 degree axis couch, model MT-6DAC (K031866)

Device Classification Name: Powered radiation therapy patient support assembly

Regulatory Class: Class II

Intended Use:

The Table Tilt Device is an additional device for treatment tables used for radiation treatment. It enables a motorized table tilt around the lateral and longitudinal axis to compensate for patient rotation. In this fashion misalignments and shift of the patient can be precisely compensated.

Device Description:

The Table Tilt Device is a powered patient support assembly for use in radiotherapy and radiosurgery treatments. It allows the user to undertake motorized tilt adjustment of a patient misalignment to eliminate the need to manually move the patient on the table.

Substantial equivalence:

The Table Tilt Device will be verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device of Med-Tec: Med-Tec 6 degree axis couch, model MT-6DAC (K031866).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2004

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstraße 8
85551 Heimstetten
GERMANY

Re: K033316
Trade/Device Name: Table Tilt Device
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy
patient support assembly
Regulatory Class: II
Product Code: 90 JAI
Dated: February 25, 2004
Received: March 9, 2004

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

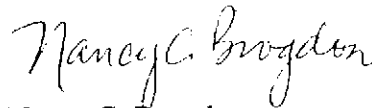
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033316

Device Name: Table Tilt Device

Indications For Use:

The **Table Tilt Device** is a device used to compensate rotational patient misalignment (roll and pitch) in a linear accelerator environment for stereotactic radiosurgery or radiotherapy procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

David R. Lyman
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K033316